Serial No. 10/586,801

Amendment dated December 8, 2010

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

- 1. (Currently amended) Pharmaceutical composition A tablet comprising particles of metformin and particles of fibrate, wherein the eomposition tablet comprises about 70% to about 95% by weight of fibrate and metformin combined together, and about 5% to about 30% by combined weight of at least one pharmaceutically acceptable excipient, wherein said excipient consists of one or more pharmaceutically acceptable excipients, wherein the weight ratio of metformin to fibrate is comprised between 500:90 and 850:35, and wherein the fibrate is selected from the group consisting of: fenofibrate, fenofibric acid or a pharmaceutically acceptable salt or ester of fenofibric acid, and with the provision that if the weight ratio of metformin to fibrate is comprised between 500:90 and 500:65, said composition comprises a dispersion aid as a mandatory excipient.
- (Currently amended) Pharmaceutical composition The tablet according to claim 1, wherein the weight ratio of metformin to fibrate is comprised between 500:54 and 850:65.
- (Currently amended) Pharmaceutical composition The tablet according to claim 1, wherein the weight ratio of metformin to fibrate is comprised between 850:54 and 850:35.
- 4. (Currently amended) Pharmaceutical composition The tablet according to claim 1, in which at least about 70% of the fibrate is dissolved within about 15 minutes, at least about 80% of the fibrate is dissolved within about 30 minutes, at least about 85% of the fibrate is dissolved within about 45 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium containing 0.025 M sodium lauryl sulfate.
- (Currently amended) Pharmaceutical composition The tablet according to claim 1, comprising:

about 74% to about 90% by weight of fibrate and metformin combined together; and

Serial No. 10/586.801

Amendment dated December 8, 2010

about 10% to about 26% by weight of pharmaceutically acceptable excipients.

6. (Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein said fibrate is in a crystalline phase, an amorphous phase, a semi-crystalline phase, or a

semi-amorphous phase.

(Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein the fibrate is fenofibrate.

8. (Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein the fibrate is micronised or co-micronised.

(Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein the fibrate is co-micronized with a surfactant.

10. (Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein the particles of fibrate have an average size of less than about 20 μm.

11. (Cancelled)

12. (Cancelled)

13. (Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein the fibrate is in the form of nanoparticles having an average size of less than about 2000

nm.

14. (Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein metformin is in the form of the free base or one of its pharmaceutically acceptable salts.

3

Serial No. 10/586.801

Amendment dated December 8, 2010

15. (Currently amended) Pharmaceutical composition The tablet according to claim 1,

comprising 850 mg of metformin and 80 mg of fenofibrate; 850 mg of metformin and 54 mg of fenofibrate; 500 mg of metformin and 80 mg of fenofibrate; 500 mg of metformin and 54 mg of

fenofibrate; 500 mg of metformin and 40 mg of fenofibrate; 500 mg of metformin and 45 mg of

fenofibrate, 500 mg of metformin and 71 mg of fenofibrate, 850 mg of metformin and 71 mg of

fenofibrate; or 850 mg of metformin and 145 mg of fenofibrate.

16. (Currently amended) Pharmaceutical composition The tablet according to claim 1,

wherein the eomposition tablet is formulated for oral, pulmonary, rectal, ophthalmic, colonic,

parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, or topical

administration.

17. (Canceled)

18. (Canceled)

19. (Currently amended) Pharmaceutical composition The tablet of claim 17.1, which is in

the form of a tablet weighing from about 500 to about 1500 mg.

20. (Currently amended) Pharmaceutical composition The tablet according to claim 1, further

comprising one or more active substances selected from the group consisting of $\mbox{PPAR}\gamma$

activators, HMG CoA reductase inhibitors and antihypertensives.

(Cancelled)

22. (Cancelled)

23. (Withdrawn) A process for preparing a pharmaceutical composition as defined in claim 1,

wherein said pharmaceutical composition comprises granulates obtained by the process

comprising the steps of:

4

Serial No. 10/586.801

Amendment dated December 8, 2010

 a) preparing an aqueous dispersion of the fibrate, preferably in the presence of at least one binder and/or surface stabilizer;

- b) spraying the resulting dispersion onto a fluidized bed of metformin, whereby granulates are obtained:
- c) drying the resulting granulates.
- 24. (Withdrawn) A process for preparing a pharmaceutical composition as defined in claim 1, wherein said pharmaceutical composition comprises granulates obtained by the process comprises the steps of:
- a) subjecting to high-shear a mixture of metformin and the fibrate, preferably in the presence of at least one binder and/or surface stabilizer;
- b) adding water to the high-sheared mixture whereby granulates are obtained;
- c) drying the resulting granulates in a fluid bed dryer.
- 25. (Withdrawn) A process for preparing a pharmaceutical composition as defined in claim 1, wherein said pharmaceutical composition comprises granulates obtained by the process comprises the steps of:
- a) subjecting to high-shear a mixture of metformin and the fibrate, preferably in the presence of at least one binder and/or surface stabilizer;
- b) adding water to the high-sheared mixture whereby granulates are obtained;
- c) drying the resulting granulates in a one-pot system.
- (Currently amended) Pharmaceutical composition The tablet according to claim 1, wherein the weight ratio of metformin to fibrate is comprised between 500:90 and 850:54.
- (Currently amended) Pharmaceutical composition The tablet according to claim 10, wherein the particles of fibrate have an average size of less than about 10 µm.

Serial No. 10/586,801

Amendment dated December 8, 2010

 (Currently amended) Pharmaceutical composition The tablet according to claim 13, wherein the fibrate is in the form of nanoparticles having an average size of less than about 1500 nm.

 (Currently amended) Pharmaceutical composition The tablet according to claim 13, wherein the fibrate is in the form of nanoparticles having an average size of less than about 1000 nm.

- (Currently amended) Pharmaceutical composition The tablet according to claim 13,
 wherein the fibrate is in the form of nanoparticles having an average size of than about 500 nm.
- (Currently amended) Pharmaceutical composition The tablet according to claim 13, wherein the fibrate is in the form of nanoparticles having an average size of less than about 100 nm.
- (Currently amended) Pharmaceutical composition The tablet according to claim 1, obtained from granulates comprising particles of metformin and particles of fibrate, adhering to said metformin particles.